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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/580,822

05/26/2000

Gyorgy Lajos Kis

OP/V-30969A

9338

1095

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01/24/2007

NOVARTIS

CORPORATE INTELLECTUAL PROPERTY

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

EXAMINER

MCKANE, ELIZABETH L

ART UNIT

PAPER NUMBER

1744

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

09/580,822

Applicant(s)

KIS ET AL.

Examiner

Leigh McKane

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-23, 25-27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-23, 25-27 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 September 2006 has been entered.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 21-23, 25-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horlington et al. (US 4,425,345) in view of Carter (US 5,052,558) and either of Slater et al. (US 4,478,342) or McCartney et al. (US 5,460,283).

With respect to claims 21, 22, and 26, Horlington et al. teaches a method of sterilizing a closed, squeezable pharmaceutical package wherein the package is a polypropylene bottle with a cap and nozzle tip (integral dispensing tip). See col.8, line 52 to col.9, line 8. In the method of Horlington et al., an ophthalmic liquid is placed within the bottle, closed, and sterilized by autoclaving. Horlington et al. fails to disclose fabricating the cap from a material having a different modulus of elasticity from the bottle and to autoclaving at 121 °C.

Carter discloses a method of packaging and steam sterilizing (autoclaving) a pharmaceutical product with a polypropylene bottle. The autoclave sterilizes the bottles using an

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application of steam at a temperature of 121 °C. See col.4, lines 47-60. Since Horlington et al. already discloses autoclaving at a temperature of 116 °C (col.10, lines 14-15), it involves no invention to increase the temperature by 5 ° in order to reach the standard autoclaving temperature of 121 °C and would have been obvious to one of ordinary skill in the art to assure complete sterility of the ophthalmic liquid.

Slater et al. teaches a sterilizable container which may be fabricated from polypropylene (col.3, lines 50-54). It is further disclosed by Slater et al. that closure **20** is “made of a material different from that of the container neck portion, to insure that there is no unintentional bonding between the closure and the container neck during heat sterilization...” (col.4, lines 32-36). For this reason, one of ordinary skill in the art at the time of the invention would have found it obvious to fabricate the cap of Horlington et al. from a material having a different modulus of elasticity from the bottle.

MaCartney et al. discloses a polyethylene cap, for use with containers, particularly polypropylene containers. MaCartney et al. teaches that polypropylene containers and caps have the inherent characteristic of “drawing back” at the point of contact, thereby reducing the contact pressure at the seal interface and impairing or destroying the integrity of the seal. See col.1, lines 42-48. As a solution, MaCartney et al. proposes using a stiff polyethylene cap for the polypropylene bottle, which maintains long term sealing engagement between the sealing surfaces. See col.2, lines 64-67 and col.4, lines 35-39. In order to avoid the problems outlined by MaCartney et al. when using polypropylene bottles and caps, it would have been obvious to employ a polyethylene cap (a material having a different modulus of elasticity from the bottle) in the invention of Horlington et al..

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As to claims 23 and 27, it is deemed within the skill of one in the art to choose an appropriate bottle thickness for the polypropylene bottle of Horlington et al.. As these types of bottles are recognized by Horlington et al. to be convention and known in the art (col.8, lines 54-57), there is no invention in choosing a suitable wall thickness.

With respect to claims 25 and 29, the closure of Slater et al. is disclosed to be made of a "rigid" plastic material, such as polyethylene. See col.4, lines 29-30. Moreover, MaCartney et al. discloses the cap to be fabricated from polyethylene and is "stiff". High-density polyethylene is known for its rigidity and stiffness. Thus, it is deemed obvious that the polyethylene employed by both Slater et al. and MaCartney et al. is high-density.

### ***Conclusion***


4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Liebert et al. (US 5,256,154) and Vacca (US 5,373,684) both teach the terminal autoclave sterilization of pharmaceutical solutions within a bottle having a nozzle and a cap.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
18 January 2007